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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,532

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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

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DELIVERY MODE

10/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,532	Applicant(s) FURUKAWA ET AL.	
	Examiner EMILY BERNHARDT	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4, 11-14 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

The lack of unity requirement set forth in the previous office action has been modified in the manner set forth below.

Group I. Claims 1-3,5-10 and 15-17 and 19 drawn to compounds and compositions where Ar¹ is phenyl (and substituted derivatives) and Z= formula (2);

Group II. Claims 1-4,11-17 and 19 drawn to compounds and compositions where Ar¹ is phenyl (and substituted derivatives) and Z= CO₂R²;

Group III. Claims 1-3,5-10 and 15-17 and 19 drawn to compounds and compositions where Ar¹ is remaining heteroaryls and Z= formula (2);

Group IV. Claims 1-4,11-17 and 19 drawn to compounds and compositions where Ar¹ is remaining heteroaryls and Z= CO₂R²;

Group V. Claim 18 drawn to multiple uses employing compounds of I-IV.

If IV is elected applicants must elect a compound group for an examination on the merits.

Whichever group is elected applicants must elect a species embrative of the elected group.

Additionally based on species elected, further restriction is required in the following manner:

- A. where R³= hydrogen.....and alkynyl group and substituted derivatives thereof;
- B. where R³= the first 2 formulas on p.5 of claim 1;
- C. where R³= the last 3 formulas on p.5 of claim 1.

Based on species elected (compound 6) applicants have constructively elected

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Group I B.

Should applicants intend to traverse the modified unity requirement the following remarks apply. As indicated in the previous action there is no special technical feature as the compounds are of considerable structural dissimilarity not only in view of the different degrees of unsaturation permitted on the central core but also in the nature of substituents thereon which results in no fixed mandatory fragment that would yield a reasonable number of answers when conducting a preliminary electronic search. When a preliminary search was run for Ar1 having all the recited choices and Z as formula (2) more than 1000+ answers was projected. Additionally, the substituents (at Ar1, Z, R3 and Ra/Rb) cannot be said to define a contribution over the prior art given the many references cited in applicants' search report directed to varying Z and R3 choices which also contains identical or similar compounds for various uses for particular cores claimed herein.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their
different classification;
- (b) the inventions have acquired a separate status in the art due to their
recognized divergent subject matter;

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The claims which read on the above subject matter are: 1-3,5-10,15-17 and 19.

Applicants are advised that said claims will be examined fully with respect to the elected species (compound 6) and further to determine patentability of remaining claims as they pertain to the elected subject matter set forth above.

Claims 1-3,5-10,15-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The R3 definition at the bottom of p.4 requires clarification. After “alkynyl group” are the the optional substituents permitted **only** for said group or for remaining R3 choices as well.

2. Use of “arbitrarily” when preceding “substituted” throughout the claims is unclear as the term could be interpreted as meaning mandatory substitution at any location. Perhaps “optionally” was really intended.

3. Composition claim 15 recites no carrier. One needs at least 2 components for a composition.

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4. Claims 16 and 17 do not further limit the scope of claim 15 since intended uses in compound/composition claims are given no material weight. Note *In re Tuominen* 213 USPQ 89. Thus the claims should be cancelled.

The attempt to incorporate subject matter into this application by reference to various JP patents and/or publications for "essential material" is ineffective because the required wording "incorporate" and "reference" do not appear in any of the passages mentioning said references on pages 15-17. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims drafted in terms of “use” have been held to be nonstatutory. See *Clinical Products, Ltd. v. Brenner*, 149 USPQ 475 .

Claims 1-3,5-10,15-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The preparation of instant compounds via certain starting materials is incomplete in the specification as currently described. Reliance on non-US patent documents for materials and reaction preparations which is being employed herein is not in accordance with MPEP 608.01(p).

Claims 1-3,5-10,15-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the free forms and salt forms, does not reasonably provide enablement for any solvate forms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and thus use the invention commensurate in scope with these claims. There is no process enabling such a scope in the specification . Note Vippagunta provided in herein who flatly states on p.18, section 3.4 the following: “Predicting the formation of solvates or hydrates of a compound.... is complex and difficult.” Applicants' own specification confirms this since despite numerous examples presented none of the compounds were obtained as solvates. Pursuant to *In re Wands*,

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8 USPQ2d 1400, factors such as 1) direction or guidance- none is seen in the specification as to what solvent would be suitable except for water;

2) presence or absence of working examples- there is none in the present case;

3) breadth of the claims- scope is easily in the millions; and 4) quantity of experimentation needed to make or use the invention must be considered to determine if undue experimentation is present. With regard to quantity of experimentation needed, it would be enormous given compounds of the instant scope would need to be synthesized and then exhaustively crystallized from the gamut of solvents reported to form solvates in the literature, followed by an examination of the crystal structure to see if any solvate has formed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5-10,15-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama (US'550). The commonly assigned patent describes many compounds both dihydropyridines and pyridines for uses as enhancing agents for antitumor drugs. See in particular Table 1. Where no entry is given for R1 the compound is a pyridine. Note many of the compounds have the same type of cyclic

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phosphate as present in the elected species as well as substituent on the phenyl and R2-R3 choices. See in particular last species in Table 1 in cols.19-20.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit
1624